



Virginia  
Regulatory  
Town Hall

## Proposed Regulation Agency Background Document

<b>Agency Name:</b>	Department of General Services Division of Consolidated Laboratory Services
<b>VAC Chapter Number:</b>	1 VAC 30, Chapters 45 and 46
<b>Regulation Title:</b>	Certification for Non-Commercial Environmental Laboratories (Chapter 45) and Certification for Commercial Environmental Laboratories (Chapter 46)
<b>Action Title:</b>	Virginia Environmental Laboratory Certification Program
<b>Date:</b>	September 20, 2002; revised January 15, 2004

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

### Summary

*Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

The proposed regulations establish the certification program required by §2.2-1105 of the *Code of Virginia* for environmental laboratories submitting data to the Department of Environmental Quality under the state's air, water and waste laws. There are two proposed regulations, one for non-commercial environmental laboratories (Chapter 45) and one for commercial environmental laboratories (Chapter 46). Each proposed regulation is organized into two parts. Part I of each regulation contains the provisions pertaining to the administration of the program. This part describes the process that owners or operators of environmental laboratories must use to be certified and to maintain certification under the program. Part II of each regulation contains the quality assurance and quality control standards that environmental laboratories must meet to be certified under the program. The standards in Part II of Chapter 45 have been developed for Virginia non-commercial environmental laboratories. The standards in Part II of Chapter 46 are the 2002 National Environmental Laboratory Accreditation Conference standards which are incorporated by reference into the regulation.

## Basis

*Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.*

Section 2.2-1102 A 1 of the *Code of Virginia* (Title 2.2, Chapter 1) authorizes the Department of General Services to promulgate regulations as necessary to perform the duties conferred upon it by law. Section 2.2-1102 A 2 authorizes the Department of General Services to establish and collect fees when general funds are not applicable. Section 2.2-1105 gives the Division of Consolidated Laboratory Services (DCLS) the authority to promulgate regulations establishing a program for the certification of environmental laboratories.

The statutory provisions cited above can be found at the following web addresses:

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+2.2-1102>

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+2.2-1105>

Section 2.2-1105 A of the *Code of Virginia* (Title 2.2, Chapter 11) requires that DCLS establish by regulation a program to certify laboratories conducting any tests, analyses, measurements, or monitoring required pursuant to the State Air Pollution Control Board (§10.1-1300 *et seq.*), the Virginia Waste Management Act (§10.1-1400 *et seq.*) or the State Water Control Law (§62.1-44.2 *et seq.*).

Section 2.2-1105 A requires that the program include minimum criteria for the following: (1) laboratory procedures; (2) performance evaluations; (3) supervisory and personnel requirements; (4) facilities and equipment; (5) analytical quality control and quality assurance; (6) certificate issuance and maintenance; (7) recertification and decertification; and (8) granting full and partial exemptions from the program based on compliance and performance. Other criteria may be included. Section 2.2-1105 A states further that regulations shall be proposed only after national accreditation standards are adopted by the National Environmental Laboratory Accreditation Conference. The last sentence of §2.2-1105 A specifies the purpose of the program: “to ensure that laboratories provide accurate and consistent tests, analyses, measurements and monitoring so that the goals and requirements of [Virginia’s air, waste and water laws] may be met.” Section 2.2-1105 B states that once the certification program is established, laboratory certification is required before any tests, analyses, measurements, or monitoring performed by a laboratory may be used for the purposes of Virginia’s air, waste or water laws. Section 2.2-1105 C requires that a fee system be established to pay for the costs of certifying laboratories under the program. Section 2.2-1105 D requires the program to include procedures for determining the qualifications of out-of-state laboratories to conduct tests, analyses, measurements or monitoring for use in Virginia. Environmental laboratories located outside Virginia that are certified or accredited under a program determined by DCLS to be equivalent to Virginia’s program must be deemed to meet the certification requirements established under §2.2-1105. Section 2.2-1105 E requires that DCLS must deny certification to

or decertify laboratories found to be falsifying data or providing false information to support certification.

All elements of the program required by §2.2-1105 are included in the proposed regulations.

The Office of Attorney General has certified that the department possesses the statutory authority to promulgate the proposed regulations.

## Purpose

*Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.*

The proposed regulations fulfill the mandate of §2.2-1105 of the *Code of Virginia* to establish a program to certify laboratories conducting tests, analyses, measurements, or monitoring required pursuant to the State Air Pollution Control Board (§10.1-1300 *et seq.*), the Virginia Waste Management Act (§10.1-1400 *et seq.*) or the State Water Control Law (§62.1-44.2 *et seq.*). Section 2.2-1105 specifies that the purpose of the program is “to ensure that laboratories provide accurate and consistent tests, analyses, measurements and monitoring . . .” required by these laws.

Compliance with the laws of the State Air Pollution Control Board, the State Water Control Law and the Virginia Waste Management Act is determined, to a great extent, by the analysis of samples and other measurements taken of Virginia’s air, water and terrain. Accurate and consistent analysis of these samples is a critical component of the determination of compliance with Virginia’s air and water quality and waste management laws.

Prior to 1997, there were no requirements to certify laboratories conducting tests, analyses, measurements or monitoring required by Virginia’s environmental laws. The Department of Environmental Quality (DEQ) audits a limited population of wastewater laboratories as part of the Virginia Pollutant Discharge Elimination Program (VPDES). These audits are part of the overall inspection program carried out by DEQ’s water staff.

The 1997 General Assembly passed §2.1-429.01, now §2.2-1105, requiring the establishment of an environmental laboratory certification program in response to findings of the January 1997 report by the Joint Legislative Audit and Review Commission (JLARC), Review of the Department of Environmental Quality (House Document No. 67)[the Report]. JLARC in its review of the DEQ’s water program on pages 56-61 of the Report, focused on three related problems.

First, JLARC found that source-reported monitoring data were not always accurate. The DEQ determines compliance with water permits mainly through data received in Discharge Monitoring Reports (DMR). Permittees are responsible to provide these data. The DEQ reviews the quality of the DMR data received through use of performance test samples that the permittees must analyze. The JLARC report at page 57 discusses this process:

The EPA-driven Discharge Monitoring Report-Quality Assurance (DMR-QA) program serves as a check on the source-reported DMR data through use of Performance Evaluation (PE) samples sent to the analyzing laboratories (both commercial and source-run) to emulate possible effluent samples from the permitted source. This program is administered to all major sources and a handful of minor sources chosen by DEQ. The samples are analyzed by the laboratories and the results are sent back to EPA for comparison with the actual make-up of the samples. This program has been in existence since 1980 and is conducted on an annual basis. States are examined for their permitted facilities' ability to analyze all parameters correctly (meaning the results of all analyses are within the acceptable confidence interval for the actual make-up of the sample), as well as the overall level of correct analyses among the permitted facilities.

JLARC demonstrated that the ability of Virginia permittees to report data accurately had been diminishing over time. In 1995, the last completed report at the time of the Report, less than 50 percent of Virginia permittees had acceptable results for all parameters.

Second, JLARC discussed problems that DEQ had experienced over time with permittees falsifying DMR data. JLARC indicated DEQ had no systematic way to check for report falsification. While DEQ investigated when their inspectors detected possible falsification and enforced when it was found, the agency was concerned about the time it sometimes took to uncover these problems.

Third, JLARC discussed the need for and benefits of a laboratory certification program in Virginia. Because "there are no minimum requirements for operation of laboratories for VPDES sample analysis . . . this adds to the question of the validity of source-reported effluent data." The DEQ audits laboratories to determine the quality of the laboratories' data. The audits are limited both in the number of laboratories audited and in the frequency of the audits. The laboratories audited are permittee laboratories and commercial laboratories used by permittees. JLARC discussed DEQ's lack of authority to limit permittees' use of commercial laboratories that do not perform well. DEQ can address the problem only through the permittee. The permittee may then use another commercial laboratory. The problematic commercial laboratory is still free, however, to provide analytical services to other permittees who are not aware of the problems at this laboratory.

JLARC listed the benefits of a laboratory certification program on page 60 of the Report:

- direct control over analytical activity by the regulatory agency;
- greater assurance that the reported data are accurate and representative of the discharge;
- minimum standards of quality; and
- improved control of factors influencing the quality of the environment.

JLARC in Recommendation 20 of the Report, stated the following:

The General Assembly may wish to consider studying the adoption of a laboratory certification program for laboratories wishing to conduct sample analyses for environmental permit holders in the Commonwealth. The General Assembly should consider including Virginia laboratories in any national certification or accreditation programs that may be developed if these national programs are determined to be adequate to meet the needs identified for Virginia.

Section 2.2-1105 of the *Code of Virginia* was the ultimate result of this recommendation.

Section 2.2-1105 A specifies that regulations shall be proposed only after national accreditation standards are adopted by the National Environmental Laboratory Accreditation Conference (NELAC). The standards adopted by NELAC provide the minimum standards recommended by JLARC in its report. The purpose of NELAC is “to foster the generation of environmental laboratory data of known and documented quality in a cost-effective manner through the development of nationally accepted standards for environmental laboratory accreditation.” NELAC 2001 Standards, page 1 of Chapter 1, Policy, Program and Structure.

Environmental permittees and regulatory agencies use hundreds of standardized test methods that are required under federal environmental laws to determine compliance with environmental laws and regulations. Environmental laws set limits for pollutants being released into the air, water and soil. Test methods provide a uniform and consistent way of determining whether the sources of pollutants (industrial facilities, wastewater treatment facilities run by local governments, etc.) exceed the limits set in their permits.

The NELAC standards and individual state certification or accreditation programs for environmental laboratories use quality assurance and quality control measures to determine whether environmental laboratories operate uniformly and consistently. Quality assurance is defined by EPA’s Quality Assurance Management Group as “an integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.” NELAC 2001 Standards, page 1A-8 of the Glossary, Appendix A, Chapter 1. Quality control is defined as “the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.” NELAC 2001 Standards, *ibid*.

The certification program will provide standards and requirements for all environmental laboratories providing data required by Virginia’s environmental laws. The program initiates certification requirements for laboratories that analyze air and waste samples. It enhances laboratory audit and certification programs for water by increasing the frequency of on-site assessments of laboratory facilities for all but major wastewater facilities, and the frequency of proficiency testing for all laboratories analyzing water samples. By requiring environmental laboratories to meet standards to obtain certification, the program will encourage the production of environmental data that are consistent, accurate and comparable. The program will enhance the quality of all environmental laboratories by assisting and educating laboratories in their continuing development of good laboratory practice. In turn, the public health and environmental quality will be protected because public health and environmental management decisions will be based on data that are of high quality. Basing environmental and public health decisions on sound data is inherently cost efficient and best protects the quality of the Commonwealth’s air, water and terrain.

The frequency of current audit and certification programs will increase. Once a laboratory receives certification under the proposed program, the certification must be renewed every two years. Proficiency testing is limited under current programs. Proficiency tests must be completed successfully twice a year to attain and maintain certification under the proposed program.

Drinking water laboratories are certified by DCLS under federal and state requirements every three years. These laboratories participate in one proficiency test study per year. A proficiency

test study determines the ability of laboratory analysts to accurately analyze samples for different substances.

The DEQ audits laboratories at wastewater and water treatment facilities that hold discharge permits from DEQ and commercial laboratories that serve these permit holders. These audits are carried out every year for major sources, every two years for minor sources and every five years for small and low priority sources.

As part of the laboratory audit program for discharge permittees, DEQ requires proficiency test studies to be done once per year for major sources and selected minors. In the most recent study, 160 majors and 43 selected minors participated.

Source size is defined under Virginia’s water law and regulations as follows:

DESIGNATION	DESCRIPTION
Municipal major	≥1 million gallons per day (mgd) flow rate
Municipal minor	≥40,000 gallons per day and <1 mgd
Municipal small	≥1,000 gallons per day and <40,000 gallons per day
Industrial major	chosen on the basis of flow, potential to harm and contaminants
Industrial minor	industrial sources that are not major or small sources
Industrial small	industrial facilities with low environmental impact potential such as discharges of non-contact cooling water, sand and gravel operations, and car washes

There are 160 major sources and 1198 minor sources that have water program permits. The total number of minor sources does not include those holding general permits. These permittees generally are not required to provide data from laboratory analyses as part of their permits. The proposed laboratory certification program will cover 915 wastewater permittees. This includes all the major sources and 755 minor sources. The remaining minor sources (443) are believed to have permit conditions that require only field test data analyses. Field tests are not included in the proposed program except when the tests are performed in an environmental laboratory.

The proposed certification program will ensure that laboratories which provide data required by Virginia’s air and waste laws and regulations are capable of consistently and accurately carrying out the methods used to analyze samples. The proposed program also will ensure that more laboratories serving wastewater and water treatment plants are assessed either for the first time or on a more frequent basis.

**Substance**

*Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action’s changes.*

A summary of the proposed regulations is set out below.

1 VAC 30, Chapter 45

This chapter applies to non-commercial environmental laboratories. A summary of this regulation follows.

1. Part I of the proposed regulation addresses general requirements of the certification program for non-commercial environmental laboratories. These general requirements cover the establishment of the program, applicability of environmental laboratories, definitions, the scope of certification, general requirements, the process to apply and obtain certification, the reasons why certification would be denied, how to maintain certification status, the process to change certification scope or status, the reasons why certification might be withdrawn and the process of withdrawal of certification, appeal procedures, exemptions and fees.
2. The proposed regulation establishes the certification program on the first day of the 25th month following the regulation's effective date [1 VAC 30-45-20 B]. Non-commercial environmental laboratories must be certified prior to this date. After this date, only data from certified environmental laboratories can be used for the purposes of Virginia's air, waste and water laws. [1 VAC 30-45-20 A].
3. The regulation applies to any owner or operator of a non-commercial environmental laboratory [1 VAC 30-45-30 A].
4. An environmental laboratory is a facility or a defined place within a facility where environmental analysis is performed. Environmental analysis is any test, analysis, measurement or monitoring used for or required by Virginia's air, waste or water laws, regulations, or any permit or order issued under those laws or regulations. Environmental analysis does not include sampling and field testing and measurement. [1 VAC 30-45-40]
5. A non-commercial environmental laboratory is one where environmental analysis is performed solely for the owner. Activities that might be seen as commercial but that are considered to be non-commercial in this proposed regulation are listed in the definition. [1 VAC 30-45-40]
6. Environmental laboratories owned by federal government agencies may be certified either through Chapter 45 or by a federal primary accrediting authority to the standards established by the National Environmental Laboratory Accreditation Conference [1 VAC 30-45-30 B].
7. Environmental laboratories will have to meet the standards in Part II of the regulation to be certified. The components of the standards are personnel qualifications, proficiency testing, on-site assessment, and quality systems. The Division of Consolidated Laboratory Services (DCLS) will grant certification by program, method and analyte. For example, DCLS will certify a laboratory for the air, waste or water program, the specific methods required by the program and permits issued by the program offices, and for the individual analytes covered by the method. [1 VAC 30-45-50 and 1 VAC 30-45-60]
8. Owners or operators of non-commercial environmental laboratories must submit applications for certification within eight months after the regulation becomes effective. DCLS may determine more specific application deadlines and notify existing laboratories. Application requirements are listed and include an application fee and certification of compliance. [1 VAC 30-45-70]
9. DCLS will determine if the application package is complete and will notify the applicant laboratory of its determination. DCLS may determine that the application package is complete and

the laboratory has satisfied all requirements except on-site assessment. If this occurs and DCLS is unable to schedule the on-site assessment within the next 90 days, the agency will grant the laboratory interim certification. Except during the initial certification period, the agency will determine whether an application is complete within 60 days. [1 VAC 30-45-70 G and H]

10. DCLS will either grant or deny the application for certification. If certification is granted, a certificate will be issued to the laboratory. If certification is denied, DCLS will provide a written notice including a right to appeal the denial of certification. DCLS will deny certification if the applicant laboratory (1) does not meet the standards in Part II of the regulation, (2) falsifies data or provides false information to support certification, or (2) does not pay the required fees. [1 VAC 30-45-70 K and L]

11. Certification expires two years from the issuance date of the certificate. Environmental laboratories retain their certification by maintaining their approved quality system and participating in proficiency test studies on a regularly scheduled basis. Laboratories are also required to keep pertinent records and notify DCLS of changes in key certification criteria. [1 VAC 30-45-70 K, 1 VAC 30-45-80 and 1 VAC 30-45-90]

12. DCLS may decertify an environmental laboratory if an owner, operator or employee submits false information or data to the agency or is convicted of charges related to falsification of a report concerning laboratory analysis. DCLS may decertify an environmental laboratory when the laboratory fails to maintain the standards and quality system for which it was accredited. Decertification may be for all aspects of the certification or part of the certification. DCLS, if it must decertify a laboratory, will provide a written notice to the environmental laboratory including the reasons for the decertification. [1 VAC 30-45-100 A - C]

13. When DCLS withdraws a laboratory's certification completely, the laboratory must return its certificate to the agency. When DCLS withdraws certification in part, it will issue an addendum to the laboratory's certificate of certification. In all cases, DCLS will notify the environmental laboratory in writing and will notify the laboratory of its right to appeal the decision under the Virginia Administrative Process Act. The laboratory owner or operator may reapply for certification once the reason for decertification has been corrected. [1 VAC 30-45-100 D and E, 1 VAC 30-45-110]

14. A laboratory may apply to DCLS for a partial or full exemption from the certification program requirements. The laboratory must have met all requirements for certification for four years before DCLS will consider granting an exemption. DCLS will provide a notice in the *Virginia Register* and take comments on the request before deciding to grant or deny the application for an exemption. The exemption shall be limited to 24 months. [1 VAC 30-45-120]

15. The proposed fees and standards address two categories of environmental laboratories: laboratories that perform only simple test procedures and general environmental laboratories. Simple test procedures are defined as (1) "field testing and measurement performed in an environmental laboratory" and (2) the test procedures to determine biochemical oxygen demand, fecal and total coliform, fecal streptococci, and all solids tests (e.g., settleable, total dissolved, total, total suspended, total volatile, and total volatile suspended solids). General environmental laboratories perform tests other than simple test procedures although they may perform these tests as well.

16. When applying for initial certification and when renewing certification, owners or operators of environmental laboratories must pay a fee. The fee is computed by adding a base fee to test category fees. If the sum of these fees exceeds a specified maximum fee, the laboratory pays the

maximum fee. The base and maximum fee is different depending on whether the laboratory is defined as a simple test procedure laboratory or a general environmental laboratory. Laboratories performing only simple test procedures have a base fee of \$100 and a maximum fee of \$400. General environmental laboratories have a base fee of \$1700 and a maximum fee of \$3800. The test category fees range from \$300 to \$900. Additional fees are charged to laboratories applying for an exemption and to laboratories that apply to modify their scope of certification. If DCLS cannot provide a timely on-site assessment, the laboratory may request an approved third-party on-site inspection at their expense. DCLS believes that the use of third-party on-site assessors will only be necessary during the initial stage of the program. [1 VAC 30-45-130]

17. To be accredited, laboratories must meet the standards specified in Part II of Chapter 45. The standards cover personnel, on-site assessment, proficiency testing and quality systems.

18. Article 1 of Part II covers personnel. Every environmental laboratory must designate a person responsible for the operation of the laboratory. For general environmental laboratories, the proposed regulation requires the laboratory manager to have two years' experience either managing a laboratory or performing the analyses for which the certification is sought. For laboratories performing only simple test procedures, the proposed regulation requires the laboratory to designate a laboratory manager. Every environmental laboratory must designate a quality assurance officer who will be responsible for the laboratory's quality system and for ensuring that the system is working. When laboratory staff is limited, the laboratory manager may be the quality assurance officer or a consultant may be hired as a quality assurance officer. The quality assurance officer must have documented training or experience in quality assurance and quality control procedures. Article 1 sets out laboratory personnel requirements and management responsibilities in addition to those for the laboratory manager and quality control officer.

19. Article 2 of Part II covers on-site assessment. DCLS will perform an on-site assessment as a condition for granting certification. Poor performance on a proficiency testing sample or a proposed change to the laboratory's operations may cause DCLS to carry out additional on-site assessments. The on-site assessment personnel shall minimize disruption of the laboratory's work during the assessment. The regulation sets out provisions on what areas of the laboratory's operation would be assessed, the process to be used during the visit such as records review, the documentation used in on-site assessment, and the follow-up and reporting procedures.

20. Article 3 of Part II covers proficiency testing. The regulation requires environmental laboratories to participate in two single-blind, single-concentration proficiency test (PT) studies per year, if available, for each environmental program, matrix type, and analyte (PT field of testing) for which the laboratory wishes to obtain or maintain certification. PT studies are not available for all fields of testing, such as air testing and analysis. The laboratory must obtain PT samples from NIST or other providers approved by DCLS. Article 3 has provisions on how the study results are reported, on recordkeeping, and on the criteria for certification.

21. Article 4 of Part II covers quality system. The requirements in Article 4 are general requirements on which the quality system of an environmental laboratory must be based. The quality system should be appropriate to the type, range and volume of the testing done by the laboratory. It should be pertinent to the work of the environmental laboratory. Some of the requirements may not apply to every laboratory subject to Chapter 45. The applicant laboratory must consult DCLS when in doubt about the applicability of a requirement in Article 4.

22. The laboratory documents its quality system in a quality manual. The elements of the manual are listed in Article 4. Provisions specifying in more detail many of the elements of the

quality manual follow the list of these elements. Other components of management of the quality system include organization, records management and storage, auditing of laboratory operations, corrective actions, subcontracting, services and supplies, and complaints. The technical requirements for the quality system cover the laboratory physical environment, equipment and reference materials, test methods and standard operating procedures, procedures for demonstration of capability, data verification, documentation of standards and reagents, measurement traceability and calibration, essential quality control procedures, sample handling, acceptance and receipt, and the laboratory report.

### 1 VAC 30, Chapter 46

This chapter applies to commercial environmental laboratories. A summary of this regulation follows.

1. Part I of the proposed regulation addresses general requirements of the certification program for commercial environmental laboratories. Many of the sections in Part I of Chapter 46 are essentially the same as sections in Part I of Chapter 45. These sections concern the establishment of the program (1 VAC 30-46-20), the general accreditation requirements (1 VAC 30-46-60), provisions on the contents of the application, completeness determination, grant of interim accreditation, and on-site assessment (1 VAC 30-46-70 G through I), denial of accreditation and reapplication following denial of accreditation (1 VAC 30-46-70 L and M), maintaining accreditation (1 VAC 30-46-80), changing accreditation status (1 VAC 30-46-90), withdrawal of accreditation (1 VAC 30-46-100 A and B), and appeal procedures (1 VAC 30-46-110).

2. Chapter 46 uses the term “accreditation” instead of the term “certification.” Unlike Chapter 45, Chapter 46 uses the National Environmental Laboratory Accreditation Conference (NELAC) standards as the standards to be met by commercial environmental laboratories.

3. The regulation applies to any owner or operator of a commercial environmental laboratory. [1 VAC 30-46-30 A]

4. An environmental laboratory is a facility or a defined place within a facility where environmental analysis is performed. Environmental analysis is any test, analysis, measurement or monitoring used for or required by Virginia’s air, waste or water laws, regulations, or any permit or order issued under those laws or regulations. Environmental analysis does not include sampling and field testing and measurement. [1 VAC 30-46-40]

5. A commercial environmental laboratory is one where environmental analysis is performed for another person. A “person” is an individual, corporation, partnership, association, or other legal entity, including any government. [1 VAC 30-45-40]

6. The owner or operator of any environmental laboratory currently accredited under the NELAC standards and located in a jurisdiction outside Virginia who wishes to apply for reciprocal accreditation must apply under Chapter 46. [1 VAC 30-46-30 A]

7. The regulation applies to DCLS. DCLS will meet the requirements of the regulation through review and accreditation by a National Environmental Laboratory Accreditation Program (NELAP)-accredited federal or state accrediting authority. This process will be complete before the program is established. In addition, DCLS will meet the NELAC standards to become the primary accrediting authority for Virginia. This process shall be complete no later than one year after the effective date of the regulation. [1 VAC 30-46-30 B]

8. Any environmental laboratory owner or operator may voluntarily apply for accreditation under Chapter 46. When an environmental laboratory owner or operator must get drinking water certification under Chapter 40 of 1 VAC 30 and environmental laboratory certification under Chapter 45, the owner or operator may apply under Chapter 46 and meet the requirements of both regulations. [1 VAC 30-46-30 C and D]

9. Owners or operators of commercial environmental laboratories must submit applications for accreditation within six months after the regulation becomes effective. DCLS may determine more specific application deadlines and notify existing laboratories. Application requirements are listed and include an application fee and certification of compliance. Owners or operators of NELAC-accredited environmental laboratories located outside Virginia must apply for reciprocal accreditation no later than six months after the regulation becomes effective. [1 VAC 30-46-70]

10. Information about accredited laboratories will be provided to the NELAP database. The information to be provided is basic information about the laboratory's certification such as the technical director's name, certification status and fields of testing for which the laboratory is accredited. [1 VAC 30-46-120]

11. The regulation lists requirements for owners or operators of laboratories accredited under Chapter 46 who wish to use the NELAP accreditation status and logo. [1 VAC 30-46-130]

12. DCLS, once it is recognized by NELAP as a primary accrediting authority, may grant reciprocal accreditation to out-of-state environmental laboratories already accredited by another primary accrediting authority. The regulation describes the process that these laboratories need to use to apply for and receive reciprocal accreditation under the program. [1 VAC 30-46-140]

13. When applying for initial accreditation and when renewing accreditation, owners or operators of environmental laboratories must pay a fee. The fee is computed by adding a base fee to test category fees. If the sum of these fees exceeds a specified maximum fee, the laboratory pays the maximum fee. Chapter 46 laboratories will pay a maximum fee of \$4200. The base fee is \$2100. Test category fees range from \$300 to \$900. Additional fees are charged to laboratories that apply to modify their scope of accreditation. If DCLS cannot provide a timely on-site assessment, the laboratory may request an approved third-party on-site inspection at their expense. DCLS believes that the use of third-party on-site assessors will only be necessary during the initial stage of the program. [1 VAC 30-45-130]

14. To be accredited, laboratories must meet the 2002 NELAC standards which are incorporated by reference into Part II of Chapter 46. The standards cover personnel, on-site assessment, proficiency testing and quality systems.

## Issues

*Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.*

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General public

**Advantages.** The program provides a set of quality assurance and quality control standards that environmental laboratories must meet to be certified. Once the program is established, the certification will be required before these laboratories can provide the data required under Virginia's environmental laws. By requiring environmental laboratories to meet standards to receive and maintain certification, the program will encourage the production of environmental data that are consistent, accurate and comparable. This certification will give the general public increased confidence in the environmental laboratory data provided to the Department of Environmental Quality (DEQ).

**Disadvantages.** The proposed regulatory action presents no disadvantages to the general public.

Regulated entities

**Advantages.** There are several advantages for regulated entities. First, DEQ and the customers of the commercial laboratories will be assured that the laboratories have been reviewed to standards set by the program. This assurance should enhance the credibility of the data produced by the laboratories. Decisions that must be made using these data will be made with greater confidence. Second, an advantage for all laboratories subject to the proposed regulations and especially for small local government laboratories is the assistance and education that will be provided during the certification process. On-site assessments often provide teaching and learning opportunities for a certifying agency and the laboratory. Third, certification enhances the ability of commercial environmental laboratories to compete within the state and outside Virginia. Once accredited under Chapter 46, commercial laboratories in Virginia may apply for reciprocal accreditation in any state that has a NELAC program. The certification process under the proposed program will be the same for all commercial environmental laboratories. Each laboratory will have to meet the same general standards and pay the same costs relative to the commercial work done by the laboratory. The certification program enables the commercial laboratories to compete on an equivalent basis.

**Disadvantages.** The disadvantages are the new or increased costs for environmental laboratories to become certified and to maintain that certification.

Agency

**Advantages.** There are a number of advantages for the agency. First, the Division of Consolidated Laboratory Services (DCLS) will manage a program that will enhance the overall environmental quality programs of the Commonwealth. The program should enable DEQ to accurately assess the quality of the data produced by environmental laboratories and, in turn, the quality of the air, water and terrain in the Commonwealth. Second, the program allows DCLS to provide an additional service to DEQ. Third, DEQ and DCLS will both benefit from increased communication regarding these environmental programs. Fourth, DCLS will become one of a growing number of states which accredit environmental laboratories under a set of national standards.

**Disadvantages.** DCLS must undergo review by the National Environmental Laboratory Accreditation Conference (NELAC) to become the primary accrediting authority for NELAC standards in Virginia. Because DCLS provides laboratory services for DEQ, DCLS must also undergo a separate review by NELAC to be accredited under the standards incorporated into its own regulation. These reviews will take time and effort, and therefore will be a cost to the agency. This cost is not included in the proposed fees.

Other matters - Memorandum of Understanding between DCLS and DEQ

For two reasons, DCLS believed early in the development of the program regulations that a memorandum of understanding (MOU) between DCLS and DEQ would be a critical element of

the program. First, the purpose of the program is to certify laboratories that provide data to DEQ. Second, DEQ already audits laboratories under the water permit (VPDES) program. The two agencies needed to resolve this conflict of responsibilities. In addition, laboratories affected by both the VPDES and the new certification program had concerns about the potential duplication of review by the two agencies.

DCLS and DEQ discussed and developed an MOU in meetings during late February and March 2000. Representatives of both agencies signed the MOU in August 2000. The MOU addresses communication and coordination between the two agencies and the conflict of responsibilities mentioned earlier. The two agencies will form a workgroup to communicate on program implementation, certification and data issues. The MOU provides that DCLS will assume DEQ responsibilities for laboratory auditing under the VPDES program. This will be done after an interim transition period during which staff from the two agencies will work together. The certification program will be established at the beginning of the 25th month following the effective date of the regulation. Prior to this time, DEQ will be responsible for laboratory audits under the VPDES program. After the program is established, DCLS will be responsible for laboratory audits under the VPDES program. These audits will be a part of the certification program's review process. During the interim period, DEQ auditors will train DCLS auditors in all aspects of the requirements under VPDES. The certification program regulation, as proposed, does not include field testing; lab audits under VPDES cover field testing. To avoid duplication of tasks by the two agencies, DCLS will take over the audit of field testing at large minor and major sources.

#### Other matters – Request for Public Comment on Proposed Regulatory Language Drafted as a Result of 2003 Legislative Changes to § 2.2-1105

The 2003 General Assembly passed and the Governor signed into law changes to § 2.2-1105, the environmental laboratory certification program statute. Senate Bill 1275 added Subsection F to the statute. Subsection F allows environmental laboratories to apply for variances from the regulations. The language of Subsection F follows:

Any laboratory subject to this section may petition the Director of the Division for a reasonable variance from the requirements of the regulations promulgated under this section. The Division may grant a reasonable variance if the petitioner demonstrates to the Director's satisfaction that (i) the proposed variance will meet the goals and purposes of the provisions of this section or regulation promulgated under this section, and (ii) the variance does not conflict with federal or state law or regulations. Any petition submitted to the Director is subject to the Administrative Process Act (§ 2.2-4000 *et seq.*).

The agency is proposing regulatory language to meet the requirements of Subsection F. The proposal includes additional provisions for both Chapters 45 and 46. The proposed regulatory language can be found in the proposed regulations at 1 VAC 30-45-140 and at 1 VAC 30-46-160. The agency requests comments on the substance and language of these proposed provisions.

## Fiscal Impact

*Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget*

*activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.*

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### ENTITIES AFFECTED

Based on information provided by the Virginia Department of Environmental Quality (DEQ), the estimated number of environmental laboratories affected by these regulations is 975.

Environmental laboratories can be categorized generally. First, there are commercial or contract laboratories that provide analytical services for a fee. Second, there are environmental laboratories that are part of municipal or other government drinking water or wastewater plants. Third, there are environmental laboratories that are part of industrial plants or that serve as an analytical laboratory for several plants within the same industrial corporation.

For regulatory purposes, there are two categories of environmental laboratories. Chapter 45 applies to non-commercial environmental laboratories. This group consists of public and private laboratories operated by government agencies and by industry that perform analyses only for their own operations. There are approximately 915 of these laboratories. A large number of these laboratories (approximately 250) perform only simple test procedures. Chapter 46 applies to commercial environmental laboratories. This group consists mainly of private commercial laboratories. Approximately 60 commercial environmental laboratories serve Virginia clients; approximately 40 of these operate within Virginia.

### FISCAL IMPACT

#### Costs to Affected Entities

There are two direct and continuing costs for the affected laboratories: application fees and the purchase of proficiency test studies. Laboratories will pay application fees every two years. Laboratories will pay the costs of proficiency test studies two times a year. There may be other costs, including the costs of third-party on-site assessors.

#### 1. Application fees

By statute, the Division of Consolidated Laboratory Services (DCLS) must recover its costs through fees charged to the laboratories applying for certification. These costs will be recovered through fees paid every two years with an application.

Fees are calculated by adding test category fees to a base administrative fee. If the total of these fees exceeds a maximum fee, the laboratory pays the maximum fee. Test category fees for all environmental laboratories range from \$300 to \$900.

For fee purposes, there are two categories of non-commercial environmental laboratories under Chapter 45: general environmental laboratories and environmental laboratories that perform only simple test procedures. General environmental laboratories will pay a base fee of \$1700. The base fee is \$100 if the laboratory performs only simple test procedures. General environmental laboratories will pay a maximum fee of \$3800. The maximum fee is \$400 if the laboratory performs

only simple test procedures. Maximum annual fee costs will be \$1900 for general environmental laboratories, and \$200 for laboratories performing only simple test procedures.

Commercial environmental laboratories subject to Chapter 46 will pay a base fee of \$2100 and a maximum fee of \$4200. Maximum annual fee costs will be \$2100 for these laboratories.

To understand what many non-commercial environmental laboratories will pay in test category fees, it helps to know the typical permit requirements for Virginia Pollutant Discharge Elimination System (VPDES) permit holders. Most require data on biochemical oxygen demand (BOD), solids and ammonia. The total test category fee for these three test categories is \$950. Permits that require only simple test procedures have the lowest base and maximum fees. These permits require data on BOD and solids but not ammonia. The total test category fee for these two test categories is \$600. Many VPDES permits include provisions requiring data on metals. Depending on the number of metals test methods required, the additional test category fees would be \$300 or \$600. Some non-commercial environmental laboratories must provide data from an extensive array of test methods. In these cases, it is common to have 4 or more inorganic and metals methods each required by the permit. The fee for each of these two test categories is \$600. The fee for 4 or more organic methods is \$700.

Relationship of Application Fees to the True Cost of the Program. The environmental laboratory certification program is a new program. The fees proposed in the regulations cover the labor and non-labor costs of the program. The labor costs are defined by the number of positions assigned to the program in the state budget. The size of the program is typical for certification programs nationwide. Therefore, no estimation was done of the time it might take to review applications and perform on-site assessments for the estimated number of laboratories affected. However the maximum fees, divided by a labor cost of \$35 per hour provide a surrogate for the labor the fees represent. The maximum fees of \$4200, \$3800, and \$400 represent, at \$35 per hour of labor, 120 hours, 108.6 hours, and 11.4 hours of review time. This review time is within a reasonable range of time needed for these reviews to be completed, with the exception of the simple test procedure laboratories. The personnel at these laboratories may need more education and assistance than the more sophisticated and complex laboratory operations. The time needed per laboratory for this category of environmental laboratory may be greater than the 11.4 hours indicated by the maximum fee.

The total cost of the program to be funded by fees is \$2,070,014 (see Cost to Agency below). The agency has calculated that the estimated total of the base fees is 61% of the cost of the program. The estimated total of the base fees is the total fees paid if all laboratories paid only the base fees. The agency does not expect that the majority of the laboratories will pay maximum fees. The agency has calculated that the total cost of the program is 73% of the estimated total of the maximum fees. The estimated total of the maximum fees is the total fees paid if all laboratories pay the maximum fee.

## 2. Proficiency test studies

Proficiency test samples cost between \$50 and \$310 per sample. Sets of samples can save money. One provider's current price for sets of samples required by the DMR-QA program range from \$185 to \$595 per set. For each laboratory, the cost of each round of proficiency test samples depends on the number of analytes for which the laboratory wants to be certified. Two rounds of proficiencies are required annually. The proficiency tests are sold by private providers approved by national standards bodies and are already required under federal environmental regulation. Proficiency tests are available for all media except air. Laboratories that are part of major facilities and selected minor facilities subject to the DEQ's VPDES program must perform these tests once a

year. Laboratories seeking certification under the proposed regulation must perform the tests twice a year.

#### SUMMARY OF DIRECT AND CONTINUING COSTS.

Examples of estimated annual costs for administrative fees and proficiency test studies are as follow:

- \$350 for a simple test procedure, non-commercial laboratory (maximum fee annualized)
- \$2075 for an average non-commercial laboratory (estimated annual fee of \$1325)
- \$2381 for a non-commercial laboratory with some metals tests requirements (estimated annual fee of \$1475)
- \$2881 for a commercial laboratory with a limited range of services (estimated annual fee of \$1975)
- \$3506 for a full-service commercial laboratory (maximum fee annualized)

#### 3. On-site assessment by approved third parties

Depending on resource needs, the agency may need to use third-party assessors approved by the agency to carry out on-site assessments during the initial certification period. Under the proposed regulation, the laboratory must approve the use of third party assessors. The applicant laboratory will pay the cost of the assessment directly. The component of the cost of third-party assessors that will affect their price is time to complete the assessment and travel costs. For a full-service commercial laboratory, a charge of \$2500-3000 might not be unusual. However, for laboratories performing only simple test procedures, this cost should be considerably lower, probably under \$1000.

#### 4. Additional costs

Affected laboratories may need to spend additional money and resources to meet the certification standards and other requirements of the regulations. This may include increasing the hours of current staff to set up a quality system that would meet the standards of the regulation. Alternatively, a laboratory may hire a contractor to review and update its current quality system. Laboratories may also hire contractors to perform internal audits on an annual basis when staff is insufficient to perform these necessary audits. Many of these costs will be initial and one-time expenditures as the laboratory begins its review to become certified.

To the extent that resources allow, DCLS will provide information to assist laboratories to become certified. A template for a quality assurance manual for small local government laboratories will be made available.

#### Costs to Localities

The projected cost of the regulation for localities is not expected to be beyond that of other affected entities.

#### Costs to Agency

The costs to the agency are the costs to establish and implement the environmental laboratory certification program. The program is to be funded by fees paid to the agency by the laboratories applying under the program. The agency will not receive these fees completely until eight months

after the effective date of the program. The program must therefore begin without fees. The costs to the agency are described below. There are costs that occur before the fees are received and after the fees are received.

Environmental laboratories are required to send their fees to DCLS as part of their application packages. Applications from commercial laboratories are due no later than six months following the effective date of the program. The agency expects to receive approximately 10% of total fees from this source. Applications from non-commercial laboratories are due no later than eight months following the effective date of the program. The agency expects to receive the remaining 90% of the fees from non-commercial laboratory applicants. These fees will probably be paid during the seventh and eighth months following the effective date of the regulations.

Costs of Program Prior to Receipt of Fees. Program staff must be hired prior to the dates applications are due so that the staff will be prepared to review applications upon receipt. The costs DCLS must pay prior to receiving fees are the costs of hiring and paying staff, the one-time costs of purchasing equipment so that the staff may do their work, and the continuing costs of maintaining staff and equipment.

The program staff will consist of twelve people, including nine auditors, one manager, and two assistants. Two of these program staff will be current DCLS employees. DCLS will begin the hiring process one month prior to the effective date of the final regulations. The agency plans to stagger the hiring of staff for the program to minimize the costs of start-up. The two in-house employees will begin work one month following the effective date of the regulations along with two new employees. Three months following the effective date of the regulations, four additional staff will begin work. Finally, five months following the effective date of the regulations, the last four staff will begin work.

The start-up period is the period from the effective date of the regulations until the date set for all fees to be sent to the agency. The costs are the labor cost for the start-up period, all one-time non-labor expenses, and the non-labor continuing expenses for the start-up period. The cost of the program also includes the time expended by the DCLS financial and managerial staff in the hiring of staff, oversight of the finances of the program, and general management of the program. This cost is assessed at eight percent of the total cost. The cost of the start-up phase of the program is \$485,874. The components of this cost can be found in the following table.

DESCRIPTION OF COST	AMOUNT
Labor	\$313,408
One-time, non-labor	\$61,320
Continuing, non-labor	\$75,155
Subtotal	\$449,883
Administrative overhead (8%)	\$35,991
<b>Total</b>	<b>\$485,874</b>

DCLS intends to assume a loan to cover the cost of the start-up phase. The loan amount, rate and period are \$500,000, at 5.5% over a 5-year period. The yearly cost of the loan is \$114,607.

Costs of Program After Receipt of Fees. The program costs once the fees are received are the costs to maintain the program. The components of this maintenance are the costs of labor, non-labor expenses and administrative overhead. The total yearly cost is \$920,400. The components of this cost can be found in the following table.

ANNUAL PROGRAM COSTS DESCRIPTION	AMOUNT
Labor	\$739,545
Continuing, non-labor	\$112,677
Subtotal	\$852,222
Administrative overhead (8%)	\$68,178
<b>Total</b>	<b>\$920,400</b>

The total of the two-year cost of the program plus the two-year cost of the loan is the amount that must be covered by the fees received from the environmental laboratories. The total cost for the first two years of the program after the initial receipt of fees is \$1,840,800. The two year cost of the loan is \$229,214. The amount needed to be covered by the fees is \$2,070,014.

The activities of the certification program are to be budgeted under program code 726 and subprogram code 02. The type of funds to be used are Enterprise Funds. The fund code is 0501.

**Detail of Changes**

*Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.*

See section on Substance, above.

**Alternatives**

*Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.*

The agency considered alternatives to the standards to be used to certify environmental laboratories. The agency considered using the National Environmental Laboratory Accreditation Conference (NELAC) standards for all the laboratories applicable under the proposed regulations. These standards are the national standards developed by the states and the federal agencies, including the Environmental Protection Agency. The agency determined that using the NELAC standards for all environmental laboratories was not feasible given the opposition to this approach from many of the non-commercial laboratories affected by the program. The agency after working with an *ad hoc* advisory group on various options for the standards to be used decided on two separate sets of standards for the program, one for commercial laboratories (the NELAC standards) and one for non-commercial laboratories. The standards for the non-commercial laboratories have most of the elements contained in the NELAC standards. They do not however contain as many documentation requirements as do the NELAC standards. This two-tier system of standards appears to be the least burdensome alternative.

## Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

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### Summary Of Comments Received

Below is a summary of the comments received during two public meetings and comment periods.

1. *Impact and cost for smaller laboratories*

Comments from five organizations focused on concerns about the impact and cost of an certification program for small laboratories. The concerns center on the fact that many local government environmental laboratories have only one person doing the laboratory work and that the level of effort needed to be accredited would be too burdensome for such an operation. In turn, the cost of meeting these certification standards would also be burdensome, the commenters believed. The commenters focused on the resources needed rather than the fees to be charged under the program. The groups also stated that smaller laboratories will find it harder to meet any set of certification standards. The groups commenting were the Virginia Rural Water Association, Coeburn-Norton-Wise Regional Waste Water Treatment Authority, Bedford County Public Service Authority, the Virginia NELAC Workgroup and the Virginia Association of Municipal Wastewater Agencies.

2. *Need for a certification or accreditation program*

Comments from four organizations stated that a certification or accreditation program is needed for environmental laboratories. The groups commenting were Norshipco, Fairfax County, the Virginia Manufacturers Association, and the James River Association.

3. *Need for a tiered approach to the program*

Comments from three organizations indicated that environmental laboratories were so different in size, operation and purpose that one set of standards would not be appropriate. Instead these commenters felt that a tiered approach to the certification or accreditation process would work best. The groups commenting were Fairfax County, Sanitary Board of Bluefield and the Virginia Association of Municipal Wastewater Agencies.

4. *Concern about the use of the National Environmental Laboratory Accreditation Conference Standards*

Comments from two organizations focused on the use of NELAC standards as the basis for the program. One commenter stated that the NELAC standards were too prescriptive and cumbersome and, therefore, should not be used. The other commenter stated their belief that the statute does not require the use of the NELAC standards as a basis for the program. The groups commenting were Fairfax County and the Virginia Association of Municipal Wastewater Agencies.

5. *Need for exemptions based on compliance and performance*

Comments from two organizations supported the statutory requirement to include in the regulation provisions that would give a total or partial exemption from the requirements of the regulation. These requirements would be given only on the basis of compliance and performance. The groups commenting were the Virginia Manufacturers Association and Virginia Power.

6. Miscellaneous comments

There were several comments that came only from one organization. One commenter stated that the program should not cover laboratories that were only taking and recording readings of pH. Another commenter stated that fees should not be charged to fund the program. Instead the program should be funded through general taxation. Another commenter stated that the program needs to include provisions for reciprocity with surrounding states. Another commenter asserted that the Commonwealth's laboratory system should be covered. Another commenter believes that all types of analyses need to be included in a certification or accreditation program, not just analyses of conventional pollutants. The same commenter believes that all data submitted by accredited laboratories should include the statistical significance, or confidence level, of the data. Another commenter is concerned about the inclusion of the air program under the statute because it is so different from the waste and water programs. Currently there are no proficiency tests for air analyses, for instance.

Response To Comments Received

In developing the proposed regulations, the comments were taken into account. Two regulations have been developed in response to the concerns about the various types of laboratories to be accredited under the program. Chapter 45 is applicable to non-commercial industrial and local government laboratories. Chapter 46 is applicable to commercial laboratories. Each has been developed with the concerns and needs of the affected laboratory community in mind. The concerns of smaller laboratories were taken into account by establishing flexibility in Chapter 45 with regard to personnel and organizational requirements. The agency has developed a template for a quality assurance manual that will help smaller laboratories meet the requirements of the program. The proposed regulations provide that the quality system to be developed by the laboratory should be appropriate to the size and type of testing that the laboratory performs. The program covers only laboratory testing, analysis, measurement and monitoring and not field testing and sampling, except where field tests are analyzed in the laboratory and not in the field. As required under the implementing statute, provisions are provided in Chapter 45 for exemptions from the program based on compliance and performance. The National Environmental Laboratory Accreditation Conference standards have been used only for commercial laboratories and laboratories which are otherwise non-commercial but that provide commercial laboratory services (proposed Chapter 46).

### Clarity of the Regulation

*Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.*

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The regulations are clearly written and easily understandable by the individuals and entities affected. The agency has worked with those affected to clarify the issues and the language of the proposed regulations during the development of these regulations.

**Periodic Review**

*Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.*

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The agency will review this regulation three years after the effective date of final regulations that follow this proposal.

The specific and measurable goals the regulations are intended to achieve are as follows:

1. Data required to be submitted to the Virginia Department of Environmental Quality under the State Air Pollution Control Board (§10.1-1300 *et seq.*), the Virginia Waste Management Act (§10.1-1400 *et seq.*), and the State Water Control Law (§ 62.1-44.2 *et seq.*) are coming from laboratories certified under the standards in these regulations.

2. The laboratories subject to the proposed regulation are either being certified by the process set out in the regulations or are gaining competence in meeting the standards necessary to become certified.

**Family Impact Statement**

*Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

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It is not anticipated that these regulations will have a direct impact on families. However, there will be a positive indirect impact. The regulations will ensure that data used to comply with the Commonwealth’s environmental laws and regulations have been derived in an accurate, precise and consistent fashion. As a result, the environmental health and welfare of the Commonwealth, including its families, will be protected.